



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/202,838 01/21/00 VERDAGUER

B TSRI504.1

EXAMINER

HM12/0913

THE SCRIPPS RESEARCH INSTITUTE
10550 NORTH TORREY PINES ROAD
MAIL DROP TPC 8
LA JOLLA CA 92037

ZHOLL.S

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/202,838

Applicant(s)

VERDAGUER ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Alignment

DETAILED ACTION

Applicants' election, with traverse, of Group I (claims 1-9), and SEQ ID NO:3, in Paper No. 12, filed 7/30/01, is acknowledged.

Applicants traverse that because Group I is generic and novel, and thus has special technical feature linked with the other groups. This is not found persuasive because of the following. As set forth in the previous Office action, GenBank discloses a CsVMV nucleotide sequence (acc. #: CVU20341, 25-OCT-1995) that has at least 80% identity to 18 sequential nucleotides of the CsVMV promoter shown in the instant SEQ ID NO:3, which nucleotide sequence disclosed in GenBank renders Group I not novel. Thus, the technical feature of the polynucleotide sequence is not so special and the Groups are not so linked under PCT Rule 13.1. Additionally, the claimed methods of Groups II-IV produce different products and/or different results which are not coextensive and which do not share the same technical feature. Consequently, due to the different inventive concepts and technical features among the Groups of inventions, they are usually published separately in literature.

Thus, the restriction requirement is still deemed proper and is, therefore, made FINAL.

Applicants amendments in Paper No. 7, filed 11/30/00, is also acknowledged. However, the amendments made in the specifications have not been entered because the pages specified by applicants could not be located.

Accordingly, claims 1-15 are currently pending, but claims 10-15 are withdrawn from further consideration as being drawn to non-elected inventions.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because no paper copy and computer readable form of the Sequence Listing including such sequences are provided. Such sequences are present at page 35, and elsewhere. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Specification

The specification is objected to because of the following reasons:

The specification referred to Figures 6A-6J, Figures 7A-7B, and Figures 9A-9I, however, there are no such figures provided. Instead provided are Figures 6, 7, and 9.

An abstract is found in the parent PCT case but is not on a separate sheet. Applicant is required to submit an abstract on a separate sheet.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

It is noted that a PTO-948 was mailed with Paper No. 11, on 6/27/01. Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Pursuant to the above notification, applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action. Applicants are reminded that this is reiterated from the last Office action.

Appropriate corrections are required.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be

Art Unit: 1631

considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

The instant claims are drawn to promoters that have 80% identity to 18 sequential nucleotides of the cassava vein mosaic virus promoter shown in SEQ ID NO:3, which consists of a sequence of 526 bases of CsVMV. While the specification provides guide lines for use of SEQ ID Nos 1-16 which consists of the region of SEQ ID NO:3, it does not provide guide lines for using as promoter any nucleotide sequence that is 80% identical to 18 contiguous sequence of SEQ ID NO:3. The claims are so broad that include any sequence as short as 18 bases that is 80% identical to 18 contiguous sequence of SEQ ID NO:3. The skilled practitioner would turn to the specification for guidelines of using such sequences as promoters, however, the specification does not provide such. As such, the skilled practitioner would turn to prior arts for guidelines, however, the prior art does not show how to use a 18- base pair sequence that is 80% identical to 18 contiguous sequence of SEQ ID NO:3 for promoter and the prior art is unpredictable of using such sequence as promoter. Finally, the practitioner would turn to trial and error experimentation to practice the full scope of the claimed invention without a reasonable expectation of success. Therefore, undue experimentation becomes the burden of the practitioner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-9 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and all its dependent claims recite the phrase "capable of initiating transcription". This phrase renders the claims indefinite because it is not clear whether the claims are drawn to a latent property that requires further limitation to possess the claims property. For example, does the promoter need to be induced to be "capable of initiating transcription"?

The word "respectively" in claim 2 is vague, confusing and renders the claim indefinite. Claim 2 is apparently a Markush claim using the pattern : *selected from the group consisting of...and* However, the word "respectively" is added to the end, and as such, it is not clear exactly of what the group is consisted.

Corrections are required.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Calvert et al. (IDS document: J Gen Virol. May 1995, Vol. 76, pages: 1271-8).

Calvert et al. disclose an isolated nucleic acid molecule (a vector molecule) comprising a promoter sequence that is capable of initiating transcription of an operably linked heterologous nucleic acid sequence in a plant cell wherein said nucleotide sequence has at least 80% identity to 18 sequential nucleotides of the instant SEQ ID NO:3 (pages 1272-1273).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

In the instant case, Calvert et al. disclose an isolated nucleic acid molecule comprising the sequence of CsVMV virus. There is plenty of reasons to believe that the nucleic acid comprises a promoter sequence that is capable of initiating transcription of an operably linked heterologous nucleic acid sequence in a plant cell wherein said nucleotide sequence has at least 80% identity to 18 sequential nucleotides of the instant SEQ ID NO:3; that the plant cell can be a dicot or a monocot; and that the transcription can be initiated in a plant mesophyll tissue, phloem tissue, or root tip tissue.

The above statement is evidenced by Berdaguer et al. (IDS document: Plant Molecular Biology, 1996, Vol. 31, pages 1129-39) who disclose exactly such (page 1129, Abstract, pages 1132-1135, especially Figures 6-7).

The sequence disclosed by Calvert et al. has a 98.2% overall identity to the sequence of the instant SEQ ID NO:3 (see the alignment enclosed). However, since only two nucleotides at the 5' end and a few nucleotides at the 3' end of the sequence of SEQ ID NO:3 are not matched with the sequence of Calvert et al., it is likely that

Art Unit: 1631

these non-matches could be caused by nucleotides added in the cloning process of the viral promoter, such as the recognition site of a restriction enzyme. As a matter of fact, the 6 base pairs of nucleotides at the 3' end GAATTC is, indeed, an Eco RI recognition site. Therefore, it is the Examiner's position that the sequence disclosed by Calvert et al. comprises/has the sequence of SEQ ID NO:3.

Conclusion

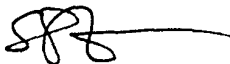
No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

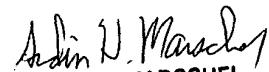
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.



S. "Joe" Zhou, Ph.D.

Patent Examiner


ARDIN H. MARSCHEL
PRIMARY EXAMINER